

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA

AMS FUND, INC. On Behalf of Himself and  
All Others Similarly Situated,

Plaintiff,

vs.

GLAXOSMITHKLINE plc, SMITHKLINE  
BEECHAM CORPORATION and JEAN-  
PIERRE GARNIER,

Defendant(s).

) Civ. Action No. \_\_\_\_\_

) CLASS ACTION

) COMPLAINT FOR VIOLATIONS OF THE  
) FEDERAL SECURITIES LAWS

) DEMAND FOR JURY TRIAL

## **INTRODUCTION**

1. This is a securities class action on behalf of all purchasers of the publicly traded securities of GlaxoSmithKline plc (“GSK” or the “Company”) between February 21, 2001 and August 5, 2004 (the “Class Period”), against GSK and certain of its officers and directors for violations of the Securities Exchange Act of 1934. GSK, along with its subsidiaries, constitute a global healthcare group engaged in the creation, discovery, development, manufacture and marketing of pharmaceutical and consumer health-related products. GSK has operations in some 117 countries, with products sold in over 130 countries. The major markets for the Company's products are the United States, Japan, France, Germany, the United Kingdom and Italy. GSK operates principally in two industry segments: Pharmaceuticals, which include prescription pharmaceuticals and vaccines and Consumer healthcare, including over-the-counter medicines, oral care and nutritional healthcare.

2. The FDA approves drugs for human use if they are safe and effective as determined through scientifically conducted clinical studies. Throughout the Class Period, Paxil was manufactured and sold by GSK and approved by the FDA for treating depression in adults. It was not approved for any condition or illness in the pediatric population.

## **JURISDICTION AND VENUE**

3. The claims asserted herein arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act, and 28 U.S.C. §1331. Venue is proper here pursuant to §27 of the 1934 Act. GlaxoSmithKline plc and SmithKline Beecham Corporation doing business as GlaxoSmithKline (collectively “GSK”) is headquartered in London, England, but conducts business in this District. GSK’s ADRs trade on the New York Stock Exchange headquartered in this District.

## **THE PARTIES**

4. Plaintiff AMS Fund Inc. acquired publicly traded securities of GSK during the Class Period as described in the attached certification, and was damaged thereby.

5. Defendant GlaxoSmithKline plc is a public company. GlaxoSmithKline plc's ADRs trade in an efficient market on the NYSE under the symbol "GSK." GlaxoSmithKline plc's ordinary shares trade in an efficient market on the London Stock Exchange. Defendant SmithKline Beecham Corporation is a Delaware corporation, which is a wholly-owned subsidiary of GlaxoSmithKline plc. GlaxoSmithKline plc was created in December 2000 when Glaxo Wellcome merged with SmithKline Beecham. Both GlaxoSmithKline plc and SmithKline Beecham, as well as all of their predecessors, subsidiaries and successors, are referred to herein collectively as "GSK."

6. Defendant Jean-Pierre Garnier ("Garnier") was CEO and Chairman of GSK throughout the Class Period. By reason of his position, Garnier had access to material inside information about GSK and was able to control directly or indirectly the acts of GSK and the contents of the representations disseminated during the Class Period by or in the name of GSK.

7. The defendants are liable, jointly and severally, as direct participants in the scheme and wrongs complained of herein. Defendants had a duty promptly to disseminate accurate and truthful information with respect to GSK's products, operations, financial condition and future business prospects or to cause and direct that such information be disseminated so that the market prices of GSK's stock and ADRs would be based on truthful and accurate information.

## **BACKGROUND AND PRE-CLASS PERIOD STATEMENTS**

8. GSK selectively released only data from favorable studies regarding Paxil and concealed data from unfavorable studies, using its employees, paid consultants, and unwitting researchers as conduits to disseminate the misleading information from these studies to the public and investors, as follows:

9. On May 30, 1998 to June 4, 1998, Drs. M.B. Keller, N.D. Ryan and B. Birmaher, et al., presented a poster at the American Psychiatric Association (“APA”) Annual Meeting in Toronto, Canada, entitled “Efficacy of [Paxil] in adolescent depression.” This poster found Paxil efficacious in children and adolescents.

10. In 1998, Drs. K.D. Wagner, B. Birmaher and G. Carlson, et al., presented a poster at the New Clinical Drug Evaluation Unit (“NCDEU”) Annual Meeting in Boca Raton, Florida, entitled “Safety of [Paxil] and imipramine in the treatment of adolescent depression.” This poster found Paxil efficacious in children and adolescents.

11. In October 1998, Drs. R. Berard and N. Ryan presented a poster at the European College of Neuropsychopharmacology Annual Meeting in Paris, France, entitled “Adolescent depression: Efficacy of [Paxil].” This poster found Paxil efficacious in children and adolescents.

12. In August 1999, Dr. C. Gagliano presented a poster at the World Congress of Psychiatry Meeting in Hamburg, Germany, entitled “[Paxil] in adolescent depression.” This poster found Paxil efficacious in children and adolescents.

13. In December 1999, Drs. G.J. Emslie, K.D. Wagner and M.A. Riddle, et al., presented a poster at the American College of Neuropsychopharmacology (“ACNP”) Annual Meeting in Acapulco, Mexico, entitled “Efficacy and safety of [Paxil] in the treatment of children and adolescents with OCD [obsessive compulsive disorder].” This poster found Paxil efficacious in children and adolescents.

14. In December 1999, Dr. Karen Wagner, one of the authors listed on the published article concerning GSK’s study to assess the safety and efficacy of Paxil in treating children and adolescents, Study 329, spoke at a meeting of GSK Neuroscience consultants, at which she discussed Study 329. She was quoted by an internal GSK newsletter as having said: “We can say that [Paxil] has both efficacy and safety data for treating depression in adolescents.”

15. On May 13-18, 2000, Drs. B. Birmaher, J.P. McCafferty and K.M. Bellew, et al., presented a poster at the APA Annual Meeting in Chicago, Illinois, entitled “Comorbid ADHD and disruptive behavior disorders as predictors of response in adolescents treated for major depression.” This poster found Paxil efficacious in children and adolescents.

16. On May 30, 2000 to June 2, 2000, Drs. K.D. Wagner, G.J. Emslie and B. Birmaher, et al., presented a poster at the NCDEU in Boca Raton, Florida, entitled “Safety of [Paxil] in the treatment of children and adolescents with OCD.” This poster found Paxil efficacious in children and adolescents.

**DEFENDANTS’ FALSE AND MISLEADING  
STATEMENTS ISSUED DURING THE CLASS PERIOD**

17. The above statements remained alive and uncorrected in the market at the beginning of the Class Period.

18. On February 21, 2001, GSK announced preliminary results for the year ended 12/21/00. GSK reported Paxil sales of £1.55 billion, an increase of 17% from the year before.

19. On May 5-10, 2001, Drs. D.A. Geller, J. Biederman and D.J. Carpenter, et al., presented a poster at the APA Annual Meeting in New Orleans, Louisiana, entitled “Comorbid psychiatric illness and response to treatment in pediatric OCD.” This poster found Paxil efficacious in children and adolescents.

20. On May 28-31, 2001, Drs. D.A. Geller, J. Biederman and K.D. Wagner, et al. presented a poster at the NCDEU Annual Meeting in Phoenix, Arizona, entitled “Comorbid psychiatric illness and response to treatment, relapse rates, and behavioral adverse event incidence in pediatric OCD.” This poster found Paxil efficacious in children and adolescents.

21. Defendants commissioned Drs. M.B. Keller, N.D. Ryan and M. Strober, et al., to write an article about one of GSK’s successful Paxil studies. It was published in an article in the Journal of the American Academy of Child and Adolescent Psychiatry, entitled “Efficacy of [Paxil]

in the treatment of adolescent major depression: A randomized, controlled trial.” This article found Paxil efficacious in children and adolescents.

22. In November 2001, GSK issued a Medical Information Letter regarding the use of Paxil to treat major depressive disorder (“MDD”) in children and adolescents, which reported studies with positive efficacy results. GSK also enclosed a published article regarding its favorable study with the Medical Information Letter.

23. On May 19-23, 2002, Drs. D. Gallagher, C. Gardiner and D.J. Carpenter presented a poster at the APA Annual Meeting in Philadelphia, Pennsylvania, entitled “Interim Results: Long-term safety of [Paxil] in pediatric patients.” This poster found Paxil efficacious in children and adolescents.

24. In June 2002, Drs. D.A. Geller, K.D. Wagner and G.J. Emslie, et al., presented a poster at the NCDEU Annual Meeting in Boca Raton, Florida, entitled “Efficacy of [Paxil] in pediatric OCD: Results of a multicenter study.” This poster found Paxil efficacious in children and adolescents.

25. In June 2002, Drs. K.D. Wagner, E. Wetherhold and D.J. Carpenter, et al., presented a poster at the NCDEU Annual Meeting in Boca Raton, Florida, entitled “Safety and tolerability of [Paxil] in children and adolescents: Pooled results from four multicenter, placebo-controlled trials.” This poster found Paxil efficacious in children and adolescents.

26. On October 22-27, 2002, Drs. D.A. Geller, K.D. Wagner and G.J. Emslie, et al., presented a poster at the American Academy of Children in Adolescent Psychiatry Annual Meeting in San Francisco, California, entitled “Efficacy of [Paxil] in pediatric OCD: Results of a multicenter study.” At that same meeting, Drs. K.D. Wagner, M.B. Stein and R. Berard, et al., presented a poster entitled “Efficacy of [Paxil] in childhood and adolescent social anxiety disorder.” Also at that meeting, Drs. K.D. Wagner, E. Wetherhold and D.J. Carpenter, et al., submitted an abstract entitled

“Safety and tolerability of [Paxil] in children and adolescents: Pooled results from five multicenter, placebo-controlled trials.” These posters and abstract found Paxil efficacious in children and adolescents.

27. In December 2002, Drs. K.D. Wagner, E. Wetherhold and D.J. Carpenter, et al., published an article in the Journal of Child and Adolescent Psychopharmacology, entitled “Safety and tolerability of [Paxil] in children and adolescents: Pooled results from four multicenter, placebo-controlled trials.” This article found Paxil efficacious in children and adolescents.

28. In December 2002, Drs. D.A. Geller, K.D. Wagner, and G.J. Emslie published an article in the Journal of Child and Adolescent Psychopharmacology, entitled “Efficacy and safety of [Paxil] in pediatric OCD: Results of a double-blind, placebo-controlled trial.” This article found Paxil efficacious in children and adolescents.

29. On December 8-12, 2002, Drs. K.D. Wagner, M.B. Stein and R. Berard, et al., presented a poster at the ACNP Annual Meeting in San Juan, Puerto Rico, entitled “Efficacy of [Paxil] in childhood and adolescent social anxiety disorder.” This poster found Paxil efficacious in children and adolescents.

30. In January 2003, Drs. A. Braconnier, R. Le Coent and D. Cohen published an article in the Journal of the American Academy of Child and Adolescent Psychiatry, entitled “[Paxil] versus clomipramine in adolescents with severe major depression: A double-blind, randomized, multicenter trial.” This article found Paxil efficacious in children and adolescents.

31. On May 17-22, 2003, Drs. K.D. Wagner, E. Wetherhold and M. Gee, et al., presented a poster at the APA Annual Meeting in San Francisco, California, entitled “Remission of pediatric social anxiety disorder with [Paxil].” This poster found Paxil efficacious in children and adolescents.

32. On May 17-22, 2003, Drs. R. Berard, K.D. Wagner, and D.J. Carpenter, et al., presented a poster at the APA Annual Meeting in San Francisco, California, entitled “SSRI therapy of pediatric patients with social anxiety disorder or OCD.” This poster found Paxil efficacious in children and adolescents.

33. In May 2003, Drs. K.D. Wagner, E. Wetherhold and M. Gee, et al. presented a poster at the NCDEU in Boca Raton, Florida, entitled “Remission of pediatric social anxiety disorder with [Paxil].” This poster found Paxil efficacious in children and adolescents.

34. The various statements in the preceding paragraphs were all sponsored by and/or known to GSK, which was instrumental in publicizing them. They were each misleading for failing to disclose other negative studies known to GSK.

35. On June 10, 2003, a British agency stated that the risk of self-harm and potentially suicidal behavior of youngsters with depression was between 1.5 and 3.2 times greater when treated with Paxil than with a placebo. A British Committee on Safety of Medicines advised that Paxil “should not be used in children and adolescents under the age of 18 years to treat depressive illness.”

36. On June 11, 2003, defendants issued a statement that “not a single person committed suicide” in the study of children taking Paxil. ““We don’t believe there’s any compelling evidence that Paxil causes suicide. If anything, it reduces suicidal tendencies”” in patients suffering from depression. This was false because it failed to disclose a number of suicide attempts in children taking Paxil.

37. On June 19, 2003, the FDA issued a Talk Paper in which it stated that it was reviewing data from studies of Paxil use in children and adolescents and, although the review of the safety data was not complete, “FDA is recommending that Paxil not be used in children and adolescents for the treatment of MDD.”



38. On June 19, 2003, defendants issued a press release which stated that “[i]n the company’s pediatric trials, which included more than 1000 patients treated with Paxil, not a single person committed suicide.” This was misleading because it failed to disclose suicide attempts.

39. On June 2, 2004, the Attorney General for the State of New York sued GSK based upon GSK’s suppression of adverse studies relevant to Paxil use to treat children and adolescents.

40. On August 5, 2004, The Wall Street Journal published an article which reported that a new analysis by the FDA had confirmed the link between SSRIs and suicidal tendencies in young people.

41. Throughout the Class Period, GSK filed a number of frivolous lawsuits to prevent other drug makers from marketing less expensive, generic versions of Paxil. A number of parties eventually filed suit against GSK challenging this practice. GSK also concealed that it engaged in unsafe manufacturing practices concerning certain drug products, including Paxil.

42. The prices of GSK’s stock and ADRs were inflated during the Class Period. These prices declined as the falsity of defendants’ statements came to light.

### **CLASS ACTION ALLEGATIONS**

43. This is a class action on behalf of those who purchased or otherwise acquired GSK common stock and ADRs during the period from February 21, 2002 to August 5, 2004 (the “Class Period”), excluding defendants, directors and officers of the Company and their families and affiliates (the “Class”). Class members are so numerous that joinder of them is impracticable. At all relevant times, the markets for GSK ADRs and common stock were efficient.

44. Common questions of law and fact predominate and include whether defendants: (i) violated the 1934 Act; (ii) omitted and/or misrepresented material facts; (iii) knew or recklessly disregarded that their statements were false; and (iv) artificially inflated GSK’s stock and ADR prices and the extent of and appropriate measure of damages.

45. Plaintiff's claims are typical of those of the Class. Prosecution of individual actions would create a risk of inconsistent adjudications. Plaintiff will adequately protect the interests of the Class. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

### **NO SAFE HARBOR**

46. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the statements pleaded herein were not specifically identified as "forward-looking statements" when made, and many were representations about the Company's present status. To the extent there were any forward-looking statements: (a) there were no meaningful cautionary statements identifying the important then-present factors that could cause actual results to differ materially from those in the purportedly forward-looking statements; and (b) the particular speakers of such forward-looking statements knew that the particular statements were false or misleading, and/or the forward-looking statements were authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

47. Any purported warnings contained in the press releases and statements quoted herein were generic and unparticularized boilerplate statements of risks, and thus lacked the meaningful cautionary language necessary to insulate any purportedly forward-looking statements.

### **FIRST CLAIM FOR RELIEF**

#### **For Violation of Section 10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

48. Plaintiff repeats the allegations set forth above.

49. Defendants violated §10(b) and Rule 10b-5 by:

(a) Employing devices, schemes and artifices to defraud;

(b) Making untrue statements of material facts and omitting to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and

(c) Engaging in acts, practices and a course of business that operated as a fraud or deceit upon the Class in connection with their purchase or acquisition of GSK stock and ADRs.

50. Class members were damaged. In reliance on the integrity of the market, they paid artificially inflated prices for GSK stock and ADRs.

51. The undisclosed adverse information concealed by defendants during the Class Period is the type of information which, because of SEC regulations, regulations of the national stock exchanges and customary business practice, is expected by investors and securities analysts to be disclosed and is known by corporate officials and their legal and financial advisors to be the type of information which is expected to be and must be disclosed.

52. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for GSK stock and ADRs. Plaintiff and the Class would not have purchased GSK stock and ADRs at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

## **SECOND CLAIM FOR RELIEF**

### **For Violation of Section 20(a) of the 1934 Act Against All Defendants**

53. Plaintiff repeats the allegations set forth above.

54. Garnier acted as a controlling person of GSK within the meaning of §20(a) of the 1934 Act as alleged herein. By virtue of his high-level position, participation in and/or awareness of GSK's operations and/or intimate knowledge of its internal financial condition and business practices, Garnier had the power to influence and control and did influence and control, directly or

indirectly, the decision-making of GSK, including the content and dissemination of the various statements which plaintiff contends are false and misleading. GSK controlled Garnier and all of its employees. Garnier was provided with or had unlimited access to copies of GSK's internal studies, reports, press releases, public filings and other statements alleged by plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

55. In particular, Garnier had direct involvement in or intimate knowledge of the day-to-day operations of GSK and therefore is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

56. As set forth above, the defendants violated §10(b) of the 1934 Act and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, these defendants are liable pursuant to §20(a) of the 1934 Act.

57. As a direct and proximate result of the wrongful conduct of defendants, plaintiff and other members of the Class suffered damages in connection with their purchase of GSK ADRs and common stock during the Class Period.

#### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action;
- B. Awarding damages, including interest;
- C. Awarding expenses, costs and attorneys' fees; and
- D. Such equitable/injunctive or other relief as the Court may deem proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: May 5, 2005



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